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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,239	01/16/2002	Melissa M. Batchelor	RM.7CP	8033
29296	7590	10/06/2004	EXAMINER	
JULIA CHURCH DIERKER DIERKER & ASSOCIATES, P.C. 3331 W. BIG BEAVER RD. SUITE 109 TROY, MI 48084-2813			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/052,239	BATCHELOR ET AL.
	Examiner	Art Unit
	David M. Naff	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 20 July 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-19, 30 and 31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 7/3/02.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

In a response of 7/20/04 to a restriction requirement of 6/22/04, applicants elected Group I claims 1-19, 30 and 31 with traverse.

The traverse merely stated that the election was with traverse  
5 and presented no reasons in support of the traverse. The restriction requirement is still considered proper, and is adhered to as made final.

Claims 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being  
10 no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/20/04.

Claims examined on the merits are 1-19, 30 and 31.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

15 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with  
20 which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 and 13 are rejected under 35 U.S.C. 112, first  
paragraph, because the specification, while being enabling for a  
biomimetic catalytic agent as required by 9 and a lipophilic salt as  
25 required by claim 14, does not reasonably provide enablement for other  
biomimetic catalytic agents and lipophilic salts. The specification  
does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification fails to enable a biomimetic catalytic agent other than that of claim 9 and a salt other than that of claim 14. It 5 would be speculation and unpredictable as to results that will be obtained when using a biomimetic agent and salt substantially different than used in the working embodiment.

***Claim Rejections - 35 USC § 112***

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 1-19, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Bridging lines 2 and 3 of claim 1 and where recited in other claims "nitrite reductase-like activity" is uncertain as to meaning and scope. Being "like" nitrite reductase is relative and subjective, and it would be uncertain as to catalytic agents that are like and not like nitrite reductase.

25 In claim 2 and where recited in other claims "biocatalytic agent" is uncertain as to meaning and scope. An agent that is biocatalytic

and not biocatalytic is relative and subjective, and will be matter of individual interpretation.

In line 3 of claim 4 and where required in other claims, it is unclear as to the type of activity possessed by "xanthine oxidase".

5 Is the activity nitrite reductase, nitrite reductase-like, nitrate reductase or nitrosothiol reducing activity.

In claim 6 and where recited in other claims "biomimetic catalytic agent" is uncertain as to meaning and scope. The line of demarcation between biomimetic and non-biomimetic catalytic agents is  
10 uncertain.

In line 3 of claim 7 and where recited in any other claim "and other nitrogen-containing blood species to nitric oxide" is uncertain as to meaning and scope, and as to species within and not within this limitation.

15 In line 2 of claim 10, the purpose of reciting "(graphite)" after "carbon" is uncertain, and it is unclear how this limits the patentable scope of the invention. If the carbon is intended to be graphite, then only graphite should be recited. If graphite is intended to be an example of a carbon, then graphite should be  
20 deleted, and claim graphite in a dependent claim further limiting the carbon.

Bridging lines 2 and 3 of claim 13 and line 2 of claim 19, "lipophilic salts of nitrite/nitrate or nitrosothiols" is uncertain as to salts required. It is unclear how one would know when a salt is

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lipophilic and not lipophilic. Additionally, in line 2 of the claims, there is not clear antecedent basis for "the polymer matrix".

In line 2 of claim 18, there is not clear antecedent basis for "the matrix".

5 Claim 31 is confusing by being dependent on claim 32, and in line 1 there is not antecedent basis for "the medical device".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20 Claims 1-5, 10-12, 15-19, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan et al (6,569,688 B2) in view

of Blake et al (6,682,732 B1) (PCT publication date 3/9/2000) and Keyes (3,933,589), and if necessary in further view of Tedeschl et al (6,645,518 B1).

The claims are drawn to a material containing an immobilized 5 catalytic agent having nitrite reductase, nitrate reductase or nitrosothiol reductase activity that converts nitrite, nitrate or nitrosothiols to nitric oxide when in contact with blood.

Sivan et al disclose an intravascular apparatus such as a stent containing an immobilized enzyme such as a nitrogen oxide synthase to 10 produce nitric oxide (col 3, lines 45-66 and col 4, lines 40-39).

Blake et al disclose treatment of lesions with a composition containing xanthine oxidase that produces nitric oxide (col 5, lines 25-40 and col 9, lines 5-10).

Keyes discloses immobilizing xanthine oxidase (col 2, lines 50-15 51).

Tedeschl et al disclose a medical device such as a stent having a nitric oxide releasing coating (col 8, lines 30-49).

It would have been obvious to use xanthine oxidase as the nitric oxide producing enzyme immobilized on a stent as disclosed by Sivan et 20 al as suggested by Blake et al using xanthine oxidase in a composition to produce nitric oxide for lesion treatment and as further suggested by Keyes disclosing immobilizing xanthine oxidase. It would have been obvious that xantine oxidase will provide the enzyme function desired by Sevan et al. If needed, Tedeschl et al would have further 25 suggested a coating on a medical device that releases nitric oxide.

Claims 6-9, 13 and 14 are free of the prior art.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
10/4/04